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ABSTRACT

Noting that medical consent forms traditionally have been so full of medical and legal jargon that they have been impossible for even the educated layperson to understand, this paper presents a model for revising medical consent forms to make them more comprehensible. After describing the model, the paper explains each step involved in using it, and gives examples of consent forms that have been revised accordingly. In addition, the paper shows the revision of a specific form and how it was tested for readability through readability formulas, computer-based text evaluation programs, and user tests. (EL)

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CDC Technical Report No. 2

# Revising Medical Consent Forms: An Empirical Model and Test

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September 1983

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# Revising Medical Consent Forms: An Empirical Model and Test

by David S. Kaufer, Ph.D., Erwin R. Steinberg, Ph.D., and Sarah D. Toney, M.A.

Recent years have brought increasing pressure from the public and the courts for truly informed patient consents to medical treatment and surgical procedures.[1] Many courts have recognized that a patient's signature on a consent form is no assurance that the patient has received sufficient information, much less that he or she truly understood the information.[2] A Pennsylvania court articulated this principle this way:

> [S]ince the patient must rely on the physician to tell her of all the appropriate risks, the physician cannot discharge this duty by having the patient execute a form which states that the risks have been explained ....The courts will look beyond forms signed by patients to determine if the duty to inform has been discharged.[3]

For those responsible for writing, revising, filling in, or signing medical consent forms, however, there is a further problem. When the physician has determined what he or she should tell that patient, that information must still be explained "in layman's terms."[4] Traditionally, consent forms have been so full of medical and legal jargon that they have been impossible for even the educated layperson to understand; for most people, signing them has been a meaningless ritual.

For several years, the members of the Communication Design Center at Carnegie-Mellon University have revised medical consent forms to make them understandable. For example, in 1982, the staff at the Center rewrote a series of medical and surgical consent forms widely used in hospitals.[5] The Center's experience has led to the development of a model for revising these documents.

In effect, this article is a manual for revising medical consent forms.

In this article, we present the model, explain each step, and give examples of the consent forms that we have revised. Finally, we revise a single form according to the model and test it for improved readability (via readability indices and computerized syntactic and lexical analyses) and comprehensibility (as assessed by the number of correct responses to questions, and by response time). This article is, in effect, a manual for revising medical consent forms.

At first glance, the model that is discussed here may seem little more than a "laundry list" of unrelated, although sensible, stylistic do's and don'ts. In fact, unlike such a random list, the questions raised by the model and the order in which they are raised reflect the authors' theory of the interactive contribution of verbal and visual cues to the reader's comprehension of medical consent forms. One could imagine a professional editor raising some or all of these questions on an ad hoc basis, without a clear understanding of how the information provided by these questions is ordered and mutually reinforcing.

## Using the Model

In revising consent forms, one should think about the set of consent forms already in use, not single forms in isolation. One may discover that two forms are used together so often that they should be combined. For example, consents to release information from alcohol treatment programs and from drug abuse programs can be covered in a single form. Similarly, one can combine a patient's release form for refusal of blood or treatment on religious grounds with a similar release form for a spouse or relative, for those occasions where the patient is not competent to sign. Conversely, one should evaluate whether an existing simple form should be rewritten, such as a consent form for ambulatory care which requires a patient to consent to both the examination and the treatment at the same time. Before examination and diagnosis, however, a physician cannot specify the treatment that will be indicated. Thus, any such consent form that a patient signs could be challenged later in court. In this case, we wrote two consent forms: one for examination and one for treatment. In another instance, we deleted a section on donation of organs and tissue in an authorization for autopsy because there was a separate form available for that purpose.

The second major area to be considered by the person revising the form is the information provided in the form. What information about the procedure is essential for the patient to understand before he or she

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signs the form? For a useful form, all necessary information must be included. A statement like "The doctor has explained the possible risks to me" is not specific enough. Such a section should read:

> The doctor has explained to me the nature of these anesthetics, the way they will be given to me, and their usual side effects. He also explained the following risks connected with their use.

Underneath these sentences should be placed several blank lines so that the anesthesiologist can specify the attendant risks of the anesthetic.

The individual revising the forms must also consider whether any unnecessary information is included in the form. The Center found one family consent to "no extraordinary measures" that listed: arrhythmia control; life support with existing devices; use of artificial or mechanical organs; transplantation of organs and tissues (including blood and blood byproducts); invasive monitoring; parenteral nutrition; and intravenous infusion of potent vasoactive drugs. We recommended that this form be combined with a form for family consent "for all but CPR," into a new form for consenting to or refusing life support treatment. We also recommended that the "extraordinary measures" section read:

> I request that (check one):
> ____ the patient receive all appropriate means of treatment.
> ____ the patient receive all appropriate means of treatment except Cardio-Pulmonary Resuscitation (CPR).
> ____ no "Extraordinary Measures" be initiated.
> ____ "Extraordinary Measures" in effect be discontinued.
> ____ Other: (specify restrictions on treatment).

We further recommended that a separate checklist and glossary be prepared and regularly updated for doctors to consult when explaining the meaning of "extraordinary measures" and when filling in the consent form. Since no such list would be current for long, we felt that including it on the form would be inefficient because the forms would have to be updated and reprinted frequently. Because the doctor should explain each medical term in layperson's language, providing such explanations in the glossary would prove helpful to both doctor and patient.

Equally important as these considerations is the accessibility of the information under each heading. Wordy or unnecessarily technical language should be avoided. Accompanying this article are some examples of passages that were revised to make them more comprehensible to the layperson. The principle is simple: remove as much legal and medical jargon and as many words of Latin origin as possible.

Often the problem of difficult and excessive language is compounded by unwieldy sentence construction. The patient will understand the form more easily when the principal parties to the agreement are placed in syntactically prominent positions. A consent form records agreements between a physician and a patient; these agreements refer to real or conceivable actions, the consequences of these actions, and the individuals who are responsible for them. One way to insure that a consent form does all these things clearly is to put human beings (the parties to the agreement) in subject and direct object positions. For example:

> *Original:* The following attendant risks were explained by the doctor.
>
> *Revision:* The doctor explained the following risks to me.
>
> *Original:* It is the express intent of this agreement to release the hospital....
>
> *Revision:* This agreement releases the hospital...*or* I release the hospital....

Whenever possible, grammatical subjects should be linked to direct objects with simple and concise action verbs: "I release the hospital...." In the original example, the words "the doctor" do not appear in the subject position as they should, but are buried at the end in a prepositional phrase; the patient does not appear at all. In the second example, an

Figure 1

## A Model for Revising Consent Forms

I. Duplication
  a) Can two forms be combined?
  b) Can a single form be rewritten as two?

II. Information
  a) What information is essential for the patient to understand before he or she signs the form?
    1) Is any necessary information missing?
    2) Is unnecessary information included?
  b) Is the information under each heading comprehensible?
    1) Is the language wordy or unnecessarily technical?
    2) Are the principal parties to the agreement placed in syntactically prominent positions?
    3) Are the clauses coherently combined?
    4) Do the sentences vary by type and length?
    5) Do the sentences get quickly to the point?

III. Layout
  a) Does the layout highlight the essential information?
  b) Does it reflect the structure of the message?



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empty "it" fills the subject slot and a long introductory phrase needlessly postpones the key words in the sentence: "agreement" and "release."

The reviser of the form should make sure that the clauses are coherently combined. A text is easier to follow if it highlights a single topic from sentence to sentence and if the

**Long compound-complex sentences can give official forms a tone of authoritative incomprehensibility.**

grammatical relationships among the people and things involved are also sustained, whenever possible, across sentences. The following consent for delivery exemplifies the jumpy focus that should be avoided:

> The nature of various methods of delivery and procedures available in my case, the risks involved, the possible consequences and the possibility of complications have been explained to me by Dr._____, who has also explained possible alternate methods of delivery or treatment, their nature, risks, consequences and possible complications. I have been given an opportunity to ask questions about my delivery and I have no further questions at this time, but I have been informed that I may ask additional questions at any time.

In the first sentence, the topical focus seems to be on such particulars as methods of delivery, procedures and risks; the patient and doctor are introduced later. In the second sentence the focus is on the patient ("I") and the doctor seems to have disappeared from view. A revision of this passage appears later in this article.

Sentences should vary in length and type. One of the surest signs of bureaucratic prose is sentences which are consistently long, unwieldy, containing many levels of coordination (and, or, but) and subordination (if...then, that, because, hence, wherefore). Sentences that contain both coordination and subordination are called compound-complex. Long compound-complex sentences give official forms a tone of authoritative incomprehensibility, as in the following:

> Dr._____has explained to me that transfusions of blood and blood components are not always successful in producing a desirable result and that there is a possibility of ill effects from transfusions, such as the transmission of infectious hepatitis or other diseases, blood impairments, or untoward blood reactions.
>
> In consideration of this transfusion of blood and blood components, I release my physician, his associates or assistants, the hospital, its personnel and any other persons participating in my care from any responsibility whatsoever from any resulting illness or ill-effects, or reactions.

A revision should not only simplify and break the sentences into smaller units, but should also reduce compound-complex sentences into a wider variety of simple (without coordination or subordination), compound (coordination only), and complex (subordination only) sentences.

> The doctor has explained to me in general what a transfusion is and the procedures that will be used. He has also explained to me that there are possible risks involved with this transfusion, including infectious hepatitis, unexpected blood reactions and....
>
> I therefore permit the doctor or such other doctors or persons as may be needed to assist him to give me the transfusion.

The first sentence of the original form has been broken into two sentences in the revised form. The first sentence of the revision expresses the information contained in the original's coordinating clauses. The second sentence expresses the information contained in the original's subordinate clauses. In general, the sentences of a consent form should comprise a healthy assortment of simple, compound, and complex sentences. Whenever possible, the reviser should eliminate compound-complex sentences—such sentences are likely to pack too much information in too compact a space for the patient to process effectively.

Another mark of bureaucratic prose is its long wind-ups and its tendency to delay (and obscure) important information with canned introductions and verbal formulas. A frequent offender in medical consent forms is the expletive "it" as in "it is agreed that..." or "it is acknowledged that...." The force of this phrase is to depersonalize the doctor/patient relationship, and to put into the mouth of the patient an easily disavowable pontifical decree instead of a very human and personal contract. This phrase can also be used to obscure the responsibilities of parties since it is a way of keeping human agents out of subject slots. Oftentimes, if a reviser takes care to start the sentence with a relevant party, he or she will also eliminate any digressive wind-ups.

### Layout

An effective layout highlights essential information by reflecting and reinforcing the structure of the message. Even if the grammatical structure in the form for consent to delivery (discussed earlier) was revised to improve coherence, the resultant paragraph would be dense because of the length and complexity of the sentences. In the revision below, the passage has been "opened up" by attention to layout:

> Dr._____has:
> a) explained to me the various possible methods of delivery in my case;
> b) explained to me the risks involved, the possible consequences, and the possibility of complications including....
> c) given me the chance to ask questions, and I have no further questions at this time; and
> d) told me that I can ask more questions at any time.

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The revision uses fewer words, is built on a series of grammatically parallel clauses to keep consistent the relationship among the doctor, the patient, and the ideas communicated, and is laid out on the page to show the reader visually the relationship of the ideas presented: "The doctor has: explained to me...given me...and told me...." Furthermore, even though the revision is a single, long, and quite complex sentence, laying it out on the page to emphasize essential points and to allow the reader to absorb it, one idea at a time, improves comprehensibility. Thus, although the revision above contains 58 words, it is much more comprehensible than a typical 58-word sentence. It probably is almost as comprehensible as it would be if it were written as four sentences rather than one.

The last example shows how the series of questions from the model for revising these forms can lead to improvements which interact and reinforce each other to improve comprehensibility radically. Making consent forms easy to read, understand, and assimilate is particularly important, since people who are called upon to sign them are often under considerable stress.

## Applying the Model to a Specific Consent Form

This section discusses how our model took us from the original consent form P-43 (figure 2) to the revised P-43 (figure 3). The original P-43, a severely flawed form for consent to blood transfusions, had already undergone several revisions by expert writers before we laid hands on it. It seems that the "technically correct" revisions by expert writers, unguided by a theoretical understanding of the purpose of the consent form, are insufficient to bring the form to functional standards. Our model was designed to help writers make technical revisions of forms to meet these functional standards.

Figure 2

Original Form P-43

### Agreement for Blood Transfusion

To: Dr. _____ and _____ Hospital
*(attending physician)*

Date: _____ Time _____ a.m./p.m.

1. I authorize the administration of a blood transfusion to _____ and such additional
*(myself or name of patient)*
transfusions as may be deemed advisable in the judgment of the attending physician or his associates or assistants.

2. It is understood and agreed that the attending physician or his associates or assistants shall be responsible only for the performance of their own individual professional acts, and that the blood typing and the selection of compatible blood are the responsibilities of those who actually perform the necessary laboratory tests.

3. It has been explained that blood transfusions are not always successful in producing a desirable result and that there is a possibility of ill effects, including but not limited to the transmission of infectious hepatitis, or other diseases or blood impairments.

4. Also, it has been explained that emergencies may arise when it may not be possible to make adequate cross-matching tests, and that immediate need may make it necessary to use existing stocks of blood which may not include the most compatible blood types.

5. It is understood and expressly agreed that the blood supplied in accordance with this agreement is incidental to the rendition of services and that no requirement, guarantee, or warranty of fitness or quality shall apply.

Signed _____
*(patient or person authorized to consent for patient)*

Witness _____

*Duplication:* The first question that we considered was whether Form P-43 should be generalized in order to include consent to treatment beyond blood transfusions or, alternatively, whether the form should be limited in its application so as to cover only part of the transfusion process. For the purposes of our revision of the original P-43, we decided not to try to answer these questions, because a complete answer would have necessitated a full analysis of the institution using Form P-43 and the clientele that it serves. In brief, the decision to combine or multiply consent forms can hinge on such institutional variables as storage space, printing costs, time, the patience and attention span of clients, the importance of distinguishing treatments, and the consequences of failing to make such distinctions.

*Information:* We determined that all of the propositional information in the original P-43 was needed, but that the information was not presented as clearly or as concisely as it could be. In particular, we found that there were four essential points of information in the original which the patient should understand: (1) the doctor has explained all relevant information about the procedure, including benefits, risks, and the patient's right to refuse (this is information essential to any medical consent form); (2) the client has consented to one or as many transfusions as the attending physician deems advisable; (3) the lab technicians, not the attending doctors, are responsible for blood-typing and lab tests in non-emergency situations, and poor blood quality associated with blood transfu-



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sions; and (4) there are other risks, involving side effects, emergency situations, and poor blood quality associated with blood transfusions. These clauses were separated and given visual prominence in the revised form.

Next, we identified unnecessary words and deleted them. In the first paragraph of the original, the word "administration" adds no information: to authorize a blood transfusion is to authorize the administration of one. An efficient writer should just use "administer" or "authorize," but not both. Also, the words "advisable" and "in the judgment" are redundant, and the embedded sentence could be recast as sentence 2 in the revised form. We leave it to the reader to determine other examples of wordiness by comparing the revised and original forms.

Related to the problem of verbiage is the awkward placement in the sentence of the parties to the agreement. The original form obscures the parties to the agreement and their relation to one another. Only the first paragraph contains a human subject; even there, the doctor (the other party involved) is not mentioned as a direct object that follows the verb but is buried in a prepositional phrase. The remaining four paragraphs use an expletive "it" as subject and a passive verb form, followed by a long compound-complex "that" clause. The effect is to obscure the reader's understanding of the question "who is doing what to whom?" Our revision puts a human agent in every subject slot. We also revised passive construction of verbs into active ones.

The topical information should be presented in a coherent progression. Important information should ideally be cast in subject or direct object position. Unfortunately, all of the paragraphs of the original seem to shift topics abruptly because the referents of the subjects and objects abruptly shift. In the second paragraph for example, the topic seems to be "attending physician" but then shifts abruptly to "blood-typing;" in the third paragraph, the topic at first seems to be "blood transfusions" and then shifts to

Figure 3

Form P-43—Revised

## Agreement for Blood Transfusions

To: Dr. _____ and _____ _____ Hospital
*(attending physician)*

*Date:* _____ *Time:* _____ a.m./p.m.

1. *What my doctor has explained to me.*

   My doctor has explained:

   a. the procedure to be performed.
   b. the risks involved if I undergo this procedure.
   c. the risks involved if I do not undergo this procedure.
   d. that the choice to undergo or not to undergo this procedure is mine alone.

2. *What I consent to have done—one or more blood transfusions.*

   I agree to allow authorized members of the hospital staff to give me a blood transfusion or as many transfusions as they think I need.

3. *Who is responsible for making sure the blood given to me matches my own in non-emergency (routine) situations?*

   I understand that in non-emergency situations the lab technicians who perform the blood tests are responsible for determining my blood-type and for making sure I am given blood that matches my blood-type. The attending doctor, his associates or assistants are not responsible for these actions but only for their own actions toward my care.

4. *Other risks that have been explained to me.*

   a. Possible Side Effects: I understand that blood transfusions are not always successful. They may even cause undesirable side effects: hepatitis, blood disease, and blood impairments.
   b. Emergency Situations: In emergency situations, the blood bank's supply of blood will vary and there will not always be time to conduct adequate cross-matching checks. If the blood bank does not have blood of my type and time does not permit adequate cross-matching tests, the lab technicians may give me blood that is not of my own type.
   c. No Guarantee on the Quality of Blood Provided: I understand that the chief service of the blood bank is to provide blood when needed. The blood bank is not responsible for the quality of the blood it provides.*

Signed _____
*(patient or person authorized to consent for patient)*

Witness _____

*We have had conflicting opinions from attorneys on the adequacy of Point 4c above as a substitute for Point 5 on the original form. We recognize, of course, that revised forms must be adequate legally and are governed in revision by appropriate legal opinion. In this instance, we received legal approval only to discover later a differing opinion. If Point 4c above is not adequate, there would be no problem in substituting a legally adequate and more comprehensible version of Point 5 in the original form. For example, the last sentence in Point 4c could read: "No guarantees or warranties have been made to me about the outcome of the quality of the blood." That statement is much simpler and more readable than Point 5 in the original form, and should test well on lexical analyses.

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"possibility." In the revised version, topics are maintained as subjects or objects which change only when the topics change.

The reviser should introduce varied types and lengths of sentences which can aid the reader. Most sentences in the original are of one difficult length (very long, or approximately 30 words each). As we have explained, sentences that are unremittingly long, and that use compound-complex structures, stand a good chance of seeming convoluted. We revised the sentences in the original to use more sentence types (viz. simple, complex, or compound) and lengths (viz. 10-15 word sentences as well as 30-50 word sentences).

To ease the reader's task, the form should get to the point quickly. Most sentences in the original form start with the empty expletive: "it is agreed that...." We deleted these expletives and began each sentence with a noun-phrase subject.

*Layout:* Every essential point should be visually prominent. The layout of the original, however, did not give visual prominence to each essential point. Point 1, the information given to the patient, is a sine qua non of any consent form but is missing from the original version. Point 2, stating the actual consent, is buried in the first paragraph. Point 3, detailing the responsibilities of the health care providers, is visually prominent (in the second paragraph of the original) and thus needs no revision in this step. Point 4, naming the specific risks in blood transfusions, is spread across the third, fourth, and fifth paragraphs of the original form in no logical order. Furthermore, although the numbered paragraphs of the original lead the reader to five specific references, they do not lead the reader to see how these references fit together.

To highlight this essential information in the revised form, we gave a separate heading to each point. Point 4 received three subheadings corresponding with the third, fourth, and fifth paragraphs of the original. Generally, the numbered, lettered, and italicized headings affect the reader's ease of comprehension by (1) providing an apparent structure for locating and integrating information, (2) signalling the reader to adjust his or her reading speed to the amount of information presented, and (3) breaking or shortening these items into easily assimilated units. The horizontal line is a factor that distinguishes the headings and subheadings from the regular text. Horizontal lines are among the most useful means for separating information, and separating information is, in turn, among the most effective ways to highlight it visually.

## Before and After Tests

Once a revision has been made along the guidelines of our model, how does one know it enhances comprehensibility? We offer three tests to answer this question: (1) readability formulas, (2) computer-based text evaluation programs, and (3) user tests.

Before we proceed, however, we should explain the concept of testing that we employed. Evaluators frequently distinguish *formative* and *summative* testing:

> If the evaluation is performed to determine how well students have mastered various elements in a postulated hierarchy so that decisions can be made on how instruction should best proceed, then it is formative in nature.... However...if the purpose is simply to grade the student at the end of one unit before proceeding to the next, then the evaluation is summative.[6]

Thus, formative evaluation continues while a unit of instruction proceeds so that the teacher can learn how to adjust to the needs of the students. Summative evaluation occurs at the end of a unit so that the teacher can discover what the students have learned.

Documents can be evaluated similarly. If a document designer is relatively inexperienced, wants to find out what parts of a draft may cause trouble, or believes that a document may have many trouble spots or problems, he or she can formatively evaluate a draft or a document to be revised. With this technique, called a "user edit," someone who might reasonably be expected to use the final document receives a copy of the draft, and reads it aloud and uses it, commenting simultaneously on things that are unclear. It is simple to do a user edit of a manual, for example, for with such a document all one has to do is ask a potential user to follow the instructions.

> The user edit is based on a very simple idea: find someone who knows nothing about your machine and have him work with it, using only your manual as a guide; his errors and hesitations should tell you where the weak points are. To get more detailed information, it is also a good idea to ask users to talk while they work, telling what they are trying to do, what they are looking for, what gives them trouble, and what they would suggest to make the manual better.[7]

Since one does not "use" a consent form in the same sense or way that one "uses" a manual, a user edit of a consent form calls for a slightly different technique — reading the document out loud and saying *everything* that is on one's mind as one reads.[8] For example, a reader of the original form P-43 might comment:

> It is understood and agreed that ...hmmm, why both understood and agreed?...and who is agreeing, me?...so if I sign this it means that I understand and agree that....

The evaluator normally tapes such a monologue because a recording may aid the discovery of any trouble spots.

Since the issues in this form were common ones and we were quite experienced in revising consent forms and thus knew what was most likely to cause problems, we did only "summative" evaluations or "before and after" tests. Still, many revisers of medical consent forms, faced with forms that contain difficult medical concepts and terminology, and uncertain as to how a target population



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will try to make sense of them, will probably want to use formative as well as summative evaluations.

One way used by document designers to assess the success of a document is the readability formula. Inspired by the work of Flesch,[9] many experts devised readability formulas to try to quantify the readability of a text. Although there now exist many formulas that measure readability, all such formulas are especially sensitive to the number of words per sentence and the number of syllables per word. Thus, the more words per sentence and the more syllables per word, the more difficult readability is presumed to become.

As one can guess, readability formulas are highly corrigible instruments. They do not take into account, for example, the occasions on which adding longer words and longer sentences to a text can improve its comprehensibility (e.g., when a text is unduly terse and abbreviated). The Center for Reading at the University of Illinois has carefully investigated the limitations of readability formulas as an assessment of text readability.[10]

However, readability formulas can be useful if intelligently interpreted. One fact of language is the high correlation between short words and words that are commonly used. Readability formulas, which reward a text for using more short words than long ones, implicitly reward it for using common, instead of uncommon, words. In the writing of medical consent forms, there are ample opportunities to replace remote, forbidding language with a wording that is more common and colloquial. Thus, if the readability scores of an original and revised form are approximately similar, it may be an indication that the reviser has missed opportunities to make wordings simpler than they were.

It is also a fact of language that the longer a sentence is, the more risks there are that topical information will get buried in layers of coordination and subordination. Part of the skill of the consummate writer is the daring to take these risks — and succeed. A Norman Mailer or other skilled author can write sentences that are 50-300 words long and remain delightfully understandable. But the average writer does not have this skill and, for him or her, the sentence structure tends to collapse as the sentence grows in length. Thus if the readability scores of an original and a revised form are similar, it may be an indication that the reviser has missed opportunities to reduce not only sentence length but also sentence convolution.

Using four separate formulas, we calculated the readability scores for our original and revised forms. The original was assessed at 19th grade reading level or reading that would tax Ph.Ds. The revised form was assessed at 11th grade or high school reading level. Thus, the readability index seemed to show some sensitivity in reflecting differences between the original and revised forms. But we caution that readability indices should be used only with heavy doses of common sense. For example, the revised form for consent to delivery is one very long "sentence" and would be categorized as extremely difficult by any of the readability tests. Breaking it up and laying it out on the page, however, makes it much more comprehensible than a readability score would show.

Computer-based text-evaluation programs provide another means to measure the success of one's revised consent forms. We shall limit our discussion to one component of the best software so far developed for analyzing text — Bell Laboratories' *Writer's Workbench*. The *Style* component of *Writer's Workbench* can, among other things, calculate sentence length and type (simple, compound, complex, compound-complex). It can keep records of such items as initial sentence structures, passives, nominalizations, and auxiliary verbs.

Running the program *Style* on both the original and revised forms, we found that the length of sentences in the original form was consistently long (an average of 41 words, with the shortest sentence having 30 words). Our revision had successfully introduced more variation in length — with 43 percent of the sentence being less than 15 words, 36 percent being between 15 and 30 words, and the remaining 21 percent being over 30 words. In addition, the computer analysis revealed a larger number of compound-complex sentences. The revised form also had a greater variety of sentence types. Unlike the original, which had only compound-complex (80 percent) and compound (20 percent) sentences, the revised form had sentences which spanned all of the major types (43 percent simple, 36 percent complex, 7 percent compound, 14 percent compound-complex).

The verb "to be" is often used as a copulative or linking verb or auxiliary verb as part of the passive

Table 1

Mean Correct Responses and Response Times
Original and Revised Form P-43

| | Correct Answers to 5 Questions | Response Time (in Minutes) |
|---|---|---|
| Original Form | 2.36 | 2.65 |
| Revised Form | 4.52 | 1.64 |

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constructions which often inhibit readers from making quick connections between subjects and objects (e.g., it is understood); 48 percent of the verbs on the original form were "to be" verbs, compared to only 29 percent of the verbs on the revised forms.

The final revealing measure was sentence beginnings or a sentence's capacity to come quickly to the main or most important information. On the original form, 40 percent of the sentence openings were expletives or empty "it's." Only 40 percent began with "important information" noun-phrases. In the revised version, all beginning expletives were deleted, and 93 percent of the sentence beginnings were substantive noun-phrases.

Before completing our discussion of the computer analysis of forms, we should make it clear that these results are best used as post hoc interpretations. A *Writer's Workbench* analysis should probably not be used to predict what is wrong with a form. It should rather be used to help an evaluator confirm his or her suspicions.

Clearly the most important and reliable technique for evaluating the worth of a revision is to test original and revised forms on the clientele who must use them. If one cannot do this, one is best advised to test them on a sample thought to be homogeneous with the population in which the clientele fall. We assumed that undergraduate students (the easiest sample for us to obtain) might be more educated readers than the average person asked to sign a consent form. We thus assumed that we could conclude a great deal about the deficiencies of a form if this population had trouble with it.

The question for any user test is, what should users be tested on? What do they need to get from a form such that, if they get it, we can judge the form to be a good one? For medical consent forms, we decided that the main provisions of the form should be easy to understand and should make it easy for the client to report his or her understanding.

To test for ease and quickness of understanding, we gave the original P-43 to 25 undergraduate students enrolled at a small university and the revised form to a different sample of 25, chosen from that same population. We gave each subject enough time to read the form until the subject felt he or she understood it — five minutes if necessary. We then removed the forms and administered a five-question, short-answer test to measure understanding of the most important provisions. We tested not only the number of questions correctly answered but also the time it took subjects to answer all five questions. If our model for revision was effective, more subjects reading the revised form would answer more questions correctly and in less time.

Our predictions were dramatically confirmed. The 25 readers of the original answered an average of 2.36 questions correctly; the 25 readers of the revised form answered an average of 4.52 questions correctly.[11] In the first group, only one person scored four correctly; but of the second group, seventeen answered all five questions and six scored four correctly. The average response time for the first group was approximately 2½ minutes (159.16 seconds); the average response time for the second group was approximately 1½ minutes (98.64 seconds). The accompanying table demonstrates graphically the success of the revised form.

Using a standard *t*-test, we found that accuracy was significantly better than for the original version ($p < .05$). We also found that subjects responding to the revised form answered significantly more quickly than subjects responding to the original ($p < .05$).

The user test is the test that satisfies the skeptic who claims "the proof of the pudding is in the reading."

## Conclusion

A comprehensible consent form is not, of course, a guarantee that physician and patient have communicated to either's satisfaction. It is, however, at least an indication of good faith and a reflection of the physician's sincere attempt not only to enable the patient to understand, but also to educate the patient. A physician who asks a patient to sign a consent form consisting of long sentences clogged with technical medical terminology and stuffy legalisms that the patient cannot understand is asking for obedience, not consent.

The consent form is a record of the discussion that has taken place between physician and patient. A well-written consent form (i.e., one that the patient can understand) protects medical personnel, the hospital, and the patient. It also reflects the patient's trust in the physician and the hospital. Thus, a consent form is a document which reflects a very basic and sensitive relationship. It should, therefore, be as simply and as sensitively written as possible.

Finally, should litigation occur, a consent form which is unclear or confusing, signed by the patient in ignorance, may well be rejected by a court. One which is written to be readily comprehensible, however, demonstrates a sincere and thoughtful attempt by the physician and the hospital to communicate adequately with the patient.

## References


1. The history of the doctrine of informed consent is beyond the scope of this article. For further discussion of the history and goals of informed consent, see generally Schloendorff v. Society of New York Hosps., 105 N.E. 92 (N.Y. 1914) (the classic informed consent ruling by Judge Cardoza); President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions: Volume I: Report (U.S. Gov't. Printing Ofc., Washington, D.C.) (1982); Cassileth, B.R., *et al., Informed Consent — Why are Its Goals Imperfectly Realized?* New England Journal of Medicine 302(16): 896 (April 17, 1983); Grundner, T.M., *On the Readability of Surgical Consent Forms*, New England Journal of Medicine 302(16): 900 (April 17, 1980); Morrow, G.R., *How Readable Are Subject Consent Forms?* Journal of the American Medical Association 224: 56 (July 4, 1980).

2. Quantification of the amount and type of information that the physician must provide to fulfill the duty to obtain an informed consent may vary in different jurisdictions. *Compare* Bly v. Rhoads, 222 S.E.2d 783, 785 (Va. 1976) (measured against customary disclosure practices of physicians), *with* Carman v. Dippold, 379 N.E.2d 1365, 1370 (Ill. App. 1978) (measured against what a reasonable physician would disclose under same or similar circumstances) *and* Canterbury v. Spence, 464 F.2d 772, 780 (D.D.C. 1972), *cert. den.*, 93 S.Ct. 560 (1972) (duty measured by patients' need


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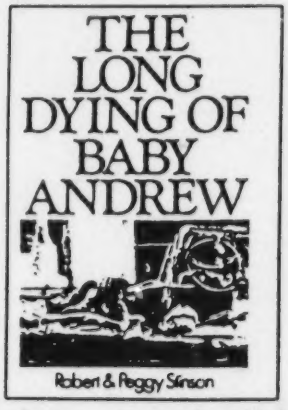
It contains a moving personal account by the parents of a son born almost four months premature, who was the "beneficiary" or the "victim" of all that scientific technology could muster for nearly six months before his death.




Based upon a previously published article,[1] the volume takes the form of diary entries by the Stinsons (the husband is a historian by profession), which has been fictionalized in terms of names and places and interspersed with later-acquired (under a state access statute) entries from the child's medical record. The authors painfully and articulately open their minds, their hearts, and their souls to us as they struggle for the six months of their son's life in the agonizing maze of legal, moral, and economic concerns into which they were unwillingly thrust. They show us the real toll of these sometimes seemingly esoteric issues on the lives of people. Not every reader will, ultimately, share the authors' quality of life orientation, which compelled them to urge withdrawal and withholding of medical interventions that by virtually any reasonable definition were extraordinary for their extremely "imperfect" offspring;[2] yet, we can all profit from the honest, human perspective that their eloquently expressed thoughts and feelings at this experience represent.

But how and why these parents resolved the treatment issue in their own consciences comprises only the more obvious, and probably less important, aspect of this book. The greater lesson is taught by their exhausting struggle with the hostile, unresponsive health care providers (both institutional and individual) with whom they were both partners and antagonists in the fate of their son. The authors paint a distressing portrait, extreme but unfortunately believable, of appalling arrogance and insensitivity by physicians, nurses, and hospital administrators. The Stinsons' story is a paradigm of an intolerable provider/patient relationship, one in which mutual trust and respect has vanished. That breakdown, as much as the pointless pain that the Stinson baby was forced to endure, is the real tragedy revealed in these pages.

The protagonist for the Stinsons in this major life crisis was one of the pediatric residents who cared for their son and for them — "cared" in the full meaning of the word. While he did not support the parents' decision (at least until the end), he did support them, as human beings with values, minds, and emotions that were entitled to dignity and respect. He took them and their wishes seriously, even if not agreeing with them or willing to carry out their proposals. This, I think, is the message that the Stinsons seek to convey — that the resolution of particular issues is of less importance to most participants in the health care enterprise than is the quality of the personal relationship that defines the structure and process through which such resolution is sought.

Robert and Peggy Stinson found the law and ethics guiding their decisionmaking to be frustratingly confusing. This is understandable, since the law and ethics in this area *are* unsettled and ambiguous. This situation, I believe, is largely desirable if we are to keep choices involving delicate considerations of both sanctity and quality of life — especially decisions that we make for others — from becoming too facile and routine. Whatever the final outcome of any specific issue, however, this brave couple teach us the value of treating each other in these difficult situations not as adversaries, but as partners, perhaps with whom to disagree and sometimes even to disobey, but deserving always of dignity, respect, and compassion.

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2. For a well stated argument in favor of aggressive treatment, see INFANTICIDE AND THE HANDICAPPED NEWBORN (D. Horan, M. Delahoyde, eds.) (1982).

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for information to decide whether to reject or accept the treatment options); *and* Getchell v. Mansfield, 489 P.2d 953, 957 (Or. 1971) (duty to disclose material risks and feasible alternatives exists as a matter of law). *See generally* Annot., 88 A.L.R.2d 1008.

3. Harrison v. Brodmerkel, No. 73-664 (Pa. C.P., Allegheny County, Pa. October 1979) *cited in* PITTSBURGH LEGAL JOURNAL 127:151, 152 (1979). *See also* Pegram v. Sisco, 406 F. Supp. 776, 779-80 (W.D. Ark. 1976).

4. The phrase "in laymen's terms," which is found in the Pennsylvania Patient Bill of Rights, 25 PA. ADMIN. CODE §103.22(b)(8) (Shepard's 1981), does not appear in AMERICAN HOSPITAL ASSOCIATION, PATIENT'S BILL OF RIGHTS (A.H.A., Chicago) (1972). However, the phrase seems to be implied. *See* Annas, G.J., *Avoiding Malpractice Suits through the Use of Informed Consent*, CURRENT PROBLEMS IN PEDIATRICS 6(5): 1 (March 1976) at 20-22.

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11. We are indebted to Davida Charney for performing the statistical tests.



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